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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,186

Applicant(s)

RICHARD ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-34 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-34 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 12-19-04 is acknowledged.

Claims included in the prosecution are 1-8, 11-34 and 37.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 11-14, 16-21, 25, 27, 31-32 and 34 are rejected under 35 U.S.C.

102(b) as being anticipated by WO 98/313,46 of record.

WO discloses polymeric micro particles for inhalation. The particles are coated with surfactant such as a phospholipid, DPPC, DPPG for example. The particles contain a variety of active principles such as hormones, both protein and non-protein type (insulin, estrogens), antiasthmotics (albuterol). The particles have density of less than 0.4 g/cm³ and a mean diameter of 5-30 microns (note pages 8, 9, 10, 20 and 21, Examples 1, 5-11).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that the particles disclosed in the 346 application are structurally different from micro particles of applicant's claims. Applicant further argues that they believe that the particles described in the 346 application are matrical microspheres and points out to pages 14, 27 and 28 in WO. These arguments are not found to be persuasive. First of all, the examiner is unable to find at these

locations the term, 'matrical microsphere'. Secondly, applicant has presented no experimental evidence to this effect.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 11-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over either EP 0706821 or FR 2753639 by themselves or in combination with either WO 98/31346 or WO 96/29998.

EP discloses polymeric micro particles coated with a surfactant (lecithin) prepared by the same method. The particles contain an active principle such as calcitonin. The mean diameter of the particles 20 nm to 100 microns with an apparent density between 0.02 g/cm³ and 0.8 g/cm³ (columns, 2, 3, 5, 6, 7, 11, Examples and claims 1, 5, 6, 11, 17 and 20).

FR discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent. The particles have a diameter of 20 nm to 500 microns with an apparent density between 0.02 g/cm³ to 0.8 g/cm³. The active agents include peptides (note pages 2, 3, 4, 8, Examples and claims 1, 2, 5, 9-14 and 16). US 6,183,783 (of record) appears to be an English equivalent for FR (abstract,

col. 3, line 13 through col. 5, line 8; col. 5, line 35 through col. 6, line 53; Examples and claims of US patent).

What is lacking in EP and FR is the mode of administration of the microspheres.

WO discloses polymeric micro particles for inhalation. The particles are coated with surfactant such as a phospholipid, DPPC, DPPG for example. The particles contain a variety of active principles such as hormones, both protein and non-protein type (insulin, estrogens), antiasthmotics (albuterol). The particles have density of less than 0.4 g/cm³ and a mean diameter of 5-30 microns (note pages 8, 9, 10, 20 and 21, Examples 1, 5-11). While WO discloses generic 'phosphoglycerides' and phospholipids, it does not teach claimed individual phosphatidylethanolamine and phosphatidylserine. However, in view of WO's exemplification using phosphatidylcholines and its generic teachings, it is deemed obvious to use any phospholipid with the reasonable expectation of success. WO also does not teach the claimed anti-asthmatic agent, beclametasone. However, in view of WO's teachings of other anti-asthmatic agents such as cromolyn, salmetrol, formeterol and albuterol, it is deemed obvious to one of ordinary skill in the art to use any known anti-asthmatic agent with a reasonable expectation of success.

WO 96 discloses polymeric coated micro particles prepared by the similar method using a super critical fluid and an organic solvent for the pulmonary administration of active agents such as calcitonin (abstract, page 5, lines 4-12, Examples and claims).

The administration of the microparticles of EP or FR via pulmonary route would have been obvious to one of ordinary skill in the art since the mode of administration is the choice of the practitioner of the art to obtain the best possible results. One of ordinary skill in the art would be motivated to administer these microparticles with a reasonable expectation of success since the references of WO 98 and 96 both teach microparticles prepared by similar methods can be administered by pulmonary route.

All the references are of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1615

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK